



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,344	10/15/2003	Ivan Osorio	011738.00149	7817

22908 7590 08/09/2005

BANNER & WITCOFF, LTD.
TEN SOUTH WACKER DRIVE
SUITE 3000
CHICAGO, IL 60606

EXAMINER

ASTORINO, MICHAEL C

ART UNIT	PAPER NUMBER
----------	--------------

3736

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,344

Applicant(s)

OSORIO ET AL.

Examiner

Michael C. Astorino

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>04, 06, & 11/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which the applicant may become aware in the specification.

Claim Objections

Claim 9 is objected to because of the following informalities: in line 1 the applicant recites the claim is dependent on claim 1, however it appears the claim should be dependent on claim 2 since the "criterion" is initially recited in claim 2. Appropriate correction is required.

Note to applicant: text inside the parenthetical, after each limitation provides a reference to the cited patent to support the examiner's rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 12-13, and 15-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Echauz et al. US Patent Number 6,678,548 B1.

Claim 1. A method for performing trial screening with a medical device system, the medical device system providing treatment to a patient with a nervous system disorder, the method comprising the steps of:

- (a) receiving a first input relating to a location of treatment therapy delivery (element number 20)
- (b) receiving a second input about a set of therapy parameters that is associated with a treatment therapy; (element numbers 60/70; see also col. 5, lines 43-53)
- (c) administering the treatment therapy in accordance with the first and second inputs; (element numbers 72, 74, 76, 78)
- (d) receiving a first indication whether the treatment therapy is acceptable to the patient and second indication whether to utilize the first and second inputs; (col. 6, lines 1-14) and
- (e) if the first indication indicates that the treatment therapy is acceptable and if the second indication indicates that the first and second inputs are to be used, applying the treatment therapy, wherein the treatment therapy is applied in a closed loop mode or an open loop mode. (column 6, lines 1-14)

In regards to claims 2 and 8 The method of claim 1, further comprising the steps of: (f) in response to step (e), determining if the treatment therapy is successful in accordance with a criterion; and (g) in response to step (f), reporting results of the treatment therapy and (h) in response to step (f), if the treatment therapy is not successful, repeating steps (a)-(g). (see figure 3, and col. 6. lines 28-62, successful and non-successful performance is inherent based on

Art Unit: 3736

the use of the computational intelligence algorithms and the posterior probability functions)

In regards to claims 3-7, see abstract and col. 5, lines 43-55.

Claim 9. The method of claim 1, wherein the criterion is selected from a group consisting of a detection frequency of the neurological event, a duration of the neurological event, an intensity of the neurological event, and an electrographic spread of the neurological event. (see abstract)

In regards to claims 12 and 13, the methods steps of claims 1 and 2 are performed by a computer-readable medium having computer-executable instructions.

Claims 15-21 are rejected on the same basis as claims 1-9 and 12-13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Echauz et al. US Patent Number 6,678,548 B1 as applied to claim 2 above, and further in view of Greene US Patent Number 6,529,774.

In regards to claims 10, 11, and 14, Echauz et al. does not disclose, The method of claim 2, wherein step (c) comprises the step of applying the treatment therapy every n.sup.th detection cluster, and wherein step (f) comprises the steps of: (i) obtaining treatment data for a first detection cluster, wherein the treatment therapy is applied; (ii) obtaining comparison data for a second detection cluster, wherein the treatment therapy is not applied, and wherein the comparison data correspond to the treatment data; and (iv) calculating a difference between the treatment data and the comparison data in order to determine the efficacy of the treatment therapy (see abstract, figure 1, and 4) but does not explicitly disclose (iii) deleting a portion of the comparison data corresponding to a blanking interval of the treatment therapy. However, Greene a reference in an analogous art does disclose (iii) deleting a portion of the comparison data corresponding to a blanking interval of the treatment therapy. (column 7, lines 51-67; column 8, lines 1-4; column 11, lines 62-67; and column 12, lines 1-12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the probabilistic framework for predicting and detecting seizure onsets in the brain and multi-therapeutic device, specific to the brain stimulation therapy in view of the brain stimulation therapy including the blanking circuit of Greene, since Greene states the use of the blanking circuit to keep the non-responsive stimulation from interfering with detection of the brain activity, column 7, lines 51-53.

Art Unit: 3736

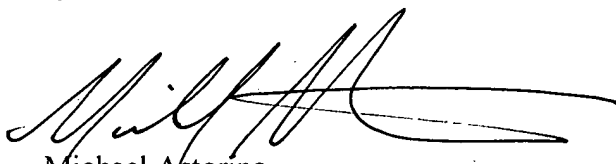
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Michael C Astorino** whose telephone number is **571-272-4723**.

The examiner can normally be reached on Monday-Friday, 8:30AM to 3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in dark ink, appearing to read 'Michael Astorino', with a long horizontal flourish extending to the right.

Michael Astorino
August 8, 2005